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The 3rd International Standard for Nystatin

1. The Standard

The 3rd International Standard (IS) for Nystatin (ISA_29384) consists of vials of approximately 100 mg of Nystatin. This preparation was established as the 3rd IS for Nystatin by the Expert Committee on Biological Standardization of the World Health Organisation in 2007 with a potency of 5710 IU/mg.

2. Biological Activity

The standard was calibrated in an international collaborative study involving 17 laboratories from different countries, against the 2nd IS for Nystatin.

The assigned potency is 5710 IU/mg for the 3rd IS for Nystatin

3. Use of the Standard

Dissolve an appropriate amount of powder with a suitable amount of solvent using gentle shaking.
Transfer the solution to a plastic tube and keep at room temperature during the assay. The solution should be used within 24 hours after reconstitution and should be kept at 25°C maximum during assays. Unused material must be discarded and not frozen for later use.

The powder in the vial is hygroscopic. Use appropriate measures to avoid water uptake during weighing.

4. Stability

Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20°C, with no predictable loss of potency over a period of 10 years. It is therefore recommended that the unopened vials should be stored at -20°C until immediately before use.

5. References

1) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series, 2007, WHO/BS/07.2072.

6. Caution

For laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. This material is not for administration to humans or animals. The corresponding safety data sheet can be accessed via the EDQM website (Reference Standards Database) or is available upon request from the EDQM (Helpdesk-FAQ section).

7. Citation

In all publications (or data sheets for kits) in which this preparation is used as an assay calibrant, it is important that the title of the preparation, code and the name and addresses of EDQM are cited correctly.

8. Product liability

The Council of Europe accordingly makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose. The product must be handled by professional persons having technical skill and at their own discretion and risk. It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the conditions of use and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted by law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

9. Disputes

In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe (EDQM) and the customer as regards the application of this contract shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

10. Signature

This document is electronically signed by:

Dr Pierre Leveau
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